

# **EXHIBIT 4**

## **(Pt. 2)**

53. Thus, throughout the Class Period, defendants led investors to believe that Organogenesis was able to manufacture Apligraf in sufficient quantities and that other sources of funding were available such that the Company would be able to achieve profitability in the foreseeable near-term. Defendants consistently reported that the Company had necessary and available funding sources, from foreseeable sales of debt and equity to both private and public investors, which would allow Organogenesis to achieve defendants' plan for sufficiency. Central to this plan was a key agreement with Novartis, Organogenesis' Apligraf marketing partner, which purportedly allowed defendants to access *at least \$20 million* through the exercise of a "put" option. This agreement purportedly would allow defendants to raise this money at any time, and thereby maintain a mega-million dollar "safety net" for the Company.

54. **Apligraf.** As stated above, throughout the Class Period, Apligraf was the Company's only commercially available product and was described by defendants as its "lead product." Defendants touted Apligraf as a unique product — according to a November 15, 1999 press release issued by the Company, it was the first and only product to containing living human cells to gain FDA PMA approval. Most if not all of the Company's revenues were at all times generated from the sale of Apligraf. Apligraf has a structure similar to human skin — consisting of living cells — and is described as a "skin construct." The product's human skin-like properties allow this product to be used by doctors to aid in the healing of certain types of skin ulcers, and other epidermal injuries.<sup>3</sup> At all times throughout the Class Period, defendants were well aware that the Company's business model was entirely dependent upon its ability to

---

<sup>3</sup> According to Organogenesis, Apligraf has an organized, two-layered structure, much like skin, and features the key components of skin — the lower dermal cells (fibroblasts), the upper epidermal cells (keratinocytes) and its key structural protein (collagen). Unlike human skin, however, Apligraf does not contain structures such as blood vessels, hair follicles and sweat glands or other cell types.

mass-produce Apligraf and market it to physicians as an “off-the-shelf,” cost-effective product that doctors could use on patients absent hospitalization.

55. By the inception of the Class Period, Apligraf was approved by the FDA for marketing in the United States for the treatment of venous leg ulcers and was pending approval for diabetic leg ulcers. At that time and during the Class Period, Apligraf was a registered trademark of Novartis, the Company’s Apligraf marketing partner. At all times during the Class Period, the Company’s marketing agreement with Novartis was consistently touted by defendants as a key to the Company’s profitability. According to defendants’ representations, the marketing agreement with Novartis (both prior to and following the time of its amendment) provided Organogenesis with enough of the revenue split generated through Apligraf sales to allow the Company to grow operations and achieve profitable growth in the foreseeable near-term. That impression was substantially reinforced when the Novartis marketing agreement was allegedly amended during the Class Period to provide even more revenues to the Company.

56. In addition to simply marketing Apligraf, Novartis was also a significant owner of Organogenesis shares, and during the Class Period owned as many as 2.8 million Company shares — or over 6% of the Organogenesis shares issued and outstanding. Novartis had acquired its shares in the Company through several private equity investments, as well as through certain funding agreements which purportedly allowed Organogenesis to sell stock to Novartis at prices predetermined and at the election of the Company.

57. The supposed ability of the Company to be able to sell stock to Novartis was also purportedly a critical part of Organogenesis’ financing, because it should have allowed defendants to raise money whenever necessary — up to \$20 million in equity financing in addition to any other sources of debt or equity financing available to the Company. Again, this

financing was also very important to investors, because it provided a purported “safety net” for Organogenesis — a reserve of cash which defendants could allegedly access as a last resort. The Novartis put option agreement was, therefore, during the Class Period, a critical part of defendants’ announced plan to achieve profitability.

58. At all times during the Class Period, therefore, Organogenesis represented that it was able to make Apligraf commercially available in a cost-effective manner which, even if the Company was forced to incur losses at the early stages of development, would allow Organogenesis to ramp up production and soon be able to fund operations from sales. Defendants consistently represented both prior to and during the Class Period that the Company was sufficiently well-funded to carry out defendants’ business plan.

59. Unbeknownst to investors, however, the reality was far different from defendants’ representations. According to the Confidential Arcari Document — created by defendant Arcari, then the Company’s Chief Financial Officer — defendant Erani, then the Company’s Chairman of the Board, sought during the Class period to have stock brokers “*manipulate the market for the Company’s stock.*” According to the Confidential Arcari Document, Erani also “encouraged the Company to prepare *overly optimistic financial projections* to existing and potential service providers.” Neither defendant Arcari, the other defendants, nor the Company ever disclosed this scheme to manipulate the Company’s stock to the public or this attempt to have the Company overstate its financial projections.

60. In furtherance of this scheme, defendants withheld from investors the true facts about the Company’s dismal and ever-deteriorating financial condition and business prospects. In the words of one former employee of Organogenesis during the Class Period, “*it was always a series of smoke and mirrors.*” Throughout the Class Period, the Company was suffering from a

host of undisclosed adverse factors which were negatively impacting its business and which would cause it to report declining financial results, materially less than the market expectations defendants had caused and cultivated. In particular:

- At all times during the Class Period, *it was not true that defendants could achieve profitability through the sale of Apligraf under the terms, or even the revised terms, of the Novartis marketing agreement*, which did not provide Organogenesis with enough of the revenues or profits provided through such Apligraf sales to offset the extremely high cost of production or to offset other undisclosed manufacturing problems such as defective products and recalls. Indeed, as defendants were well aware but did not publicly disclose, throughout the Class Period the Company was actually *losing money on every unit of Apligraf sold due to the adverse terms of the marketing agreement with Novartis*.
- Throughout the Class Period, undisclosed problems related to the manufacture and marketing of Apligraf were leading to even higher costs and further reducing profitability. Manufacturing problems and delays were retarding production scale, and marketing issues were reducing sales and damaging future sales development prospects. As plaintiffs would only learn following the Class Period, Novartis' inexperienced and inadequately trained sales force was encountering resistance throughout that time concerning the cost and complexity of its products and the actual and/or perceived difficulties in physician reimbursement for Apligraf.
- Throughout the Class Period, Organogenesis was underfunded and there was no reasonable basis to report that the Company could foreseeably fund operations based on product sales, available sources of loans, debt and/or equity sales. Indeed, defendants knew but did not disclose that, as reported by defendant Arcari in the Confidential Arcari Document, *the Company's own auditors — defendant PricewaterhouseCoopers — had in 2001 "refused to grant any consents or additional comfort letters"* for future financing initiatives and that the Company had lost credibility in the eyes of PricewaterhouseCoopers. Moreover, as defendants were well aware but failed to disclose to investors, it was not true that the Company could access the full complement of funding from Novartis as defendants consistently represented, given that certain undisclosed conditions precedent existed. Organogenesis could not meet conditions precedent to Novartis' requirement to provide at least \$10 million of its purported commitment to Organogenesis. It also was not true that other sources of funding remained available so that the Company could preserve corporate viability.
- Throughout the Class Period, defendants failed to disclose that high management turn-over and in-fighting among the senior officers and directors of the Company was having, and would continue to have a disruptive effect on the operations and oversight of Organogenesis, such that it was also not foreseeable at any time during the Class Period that Organogenesis would be able to achieve profitability in the near-term or to attain the guidance sponsored and/or endorsed by defendants.

- As a result of the aforementioned adverse conditions that defendants failed to disclose, throughout the Class Period, defendants lacked any reasonable basis to claim that Organogenesis was operating according to plan, that sufficient sources of funding were achieved and/or available to Organogenesis or that the Company could maintain profitability or even remain a viable entity in the foreseeable near-term.

61. Contrary to defendants' public statements that they expected commercial sales to increase and that they had laid the foundations for future sales development, several former employees of Organogenesis and Novartis with knowledge of the relevant facts were privy to the aforementioned problems with the marketing of Apligraf, which damaged the reputation of Apligraf and Organogenesis among purchasers and severely limited the Company's sales prospects. Although defendants were aware of these problems, they did not disclose them to investors. For example:

(a) Contrary to defendants' representations that Novartis had a "a marketing and sales force[] with *technical expertise* and distribution capability" to effectively market Apligraf, a former Tissue Engineering and Immunology Specialist with knowledge of the relevant facts who worked for Novartis Pharmaceutical Corporation, a U.S.-based business unit of Novartis, stated that although Novartis had expertise in marketing pharmaceuticals in pill form, Novartis "*had no idea what they were doing*" when it came to marketing a living-tissue product like Apligraf. According to this employee, Novartis' marketing team "had no idea about the condition, no idea how to influence a physician to change their practice to use the product because it wasn't a pill."

(b) A former director (non-Board level) on the senior management team of Organogenesis during the Class Period who attended senior management meetings and who has knowledge of the relevant facts, confirmed that *Novartis' marketing team did not have the proper training, experience or expertise in marketing a living product, such as Apligraf*, as opposed to a drug — which hindered Novartis' ability to sell Apligraf. According to this former

Director, Novartis' efforts to market Apligraf suffered significantly, with the result that the Company was required to pay for the high cost of manufacturing many more units of Apligraf than Novartis could sell. The Company thus took a "huge loss" every time that Novartis was unable to sell units of the product that Organogenesis had manufactured.

(c) According to a former Associate Director of Clinical Trials/Affairs for Organogenesis during the Class Period with knowledge of the relevant facts, the Novartis marketing team had "*no experience with a living product that had a five day shelf life,*" such as Apligraf.

62. Contrary to defendants' representations to investors that the Company expected to increase production volume and that it could achieve the mass production of Apligraf that was purportedly necessary to increase the Company's margins on sales, several former Organogenesis employees with knowledge of the relevant facts were privy to undisclosed manufacturing- and distribution-related problems with Apligraf that led to limited and delayed production, poor quality control — including at times shipping batches of Apligraf to physicians without first reviewing vital laboratory results — and, in some cases, contamination and recall of the product. As a result of these undisclosed manufacturing and distribution problems, the Company was not able to feasibly mass-produce Apligraf and the purchasers of the Company's product were steadily becoming less and less willing to order, or re-order Apligraf, thus damaging future sales prospects and adversely impacting the Company's purported attempt to achieve profitability. For example:

(a) According to a former Senior Manager of Quality Systems Compliance for Organogenesis during the Class Period with knowledge of the relevant facts, *there was "no way" that the Company could commercially mass-produce Apligraf* given the Company's inadequate

production infrastructure and processes. According to this Senior Manager of Quality Systems Compliance at Organogenesis, at the direction of defendant Sabolinski, the Company often *shipped units of Apligraf for distribution to purchasers before obtaining the results of vital laboratory testing on those units*. In fact, according to this former employee, in some cases, Sabolinski himself signed the paperwork authorizing the release of units of Apligraf before obtaining laboratory results because Quality Assurance employees refused to sign the paperwork without first viewing the laboratory results.

(b) Another former employee of the Company — a Maintenance Supervisor during the Class Period with knowledge of the relevant facts — confirmed that several times the Company *“would ship the product before they had the results back from the QC lab.”* According to this former employee, on more than one occasion, the laboratory results received after the product had already been shipped to doctors — an in some cases, after patients had already been treated with it — indicated that the shipped units had *failed chemistry testing, requiring the Company to recall the shipped units*. According to a former Organogenesis employee who was employed during the Class Period as a Quality Assurance Documentation Specialist and who has knowledge of the relevant facts, the Company experienced substantial problems growing the cells that were necessary for the production of Apligraf.

(c) According to a former employee of Novartis who was employed during the Class Period as a Tissue Engineering Specialist, and who was involved in the marketing of Apligraf, physicians who had ordered Apligraf grew frustrated and disappointed with the product because contamination of the product frequently resulted in physicians not receiving the product when necessary.



(d) According to an individual who was employed during the Class Period as a Vice President of Information Technologies for Theracom, and who worked with Novartis to set up a hotline that could be used by health care providers who used Apligraf, physicians grew reluctant to re-order Apligraf because they “couldn’t rely on it — they couldn’t rely on it coming through.”

63. Several former employees during the Class Period at various levels of the Company witnessed how high management turnover and infighting among the Company’s senior officers disrupted the operations and oversight of the Company. For example, according to the former director (non-Board level) on the senior management team of Organogenesis mentioned above, the Company suffered from, *inter alia*, “too many presidents, and too many going in different directions — a lack of leadership.”

64. According to a former Project Engineer with Organogenesis with knowledge of the relevant facts, Novartis’ sales forecasts were “*always inflated*” — a fact of which upper management at Organogenesis was well aware, but which defendants did not publicly disclose.

65. Contrary to defendants’ representations, it was not true that costs exceeded sales due to start-up costs and the high costs of low volume production, and that the Company’s margins would improve as production volume increased. According to a former Project Engineer for Organogenesis during the Class Period with knowledge of the relevant facts, it was well known by the upper management of the Company that, throughout the Class Period, Organogenesis was losing money on every sale of Apligraf because of the disadvantageous terms of the Novartis marketing agreement — under which Novartis shared revenue from Apligraf sales that was well below the product’s manufacturing cost to Organogenesis. Indeed, according to a former Maintenance Supervisor for Organogenesis during the Class Period with knowledge

of the relevant facts, this fact was known by “the whole company.” Given the terms, and the revised terms, of the Novartis marketing agreement — which caused Organogenesis to lose money on every unit of Apligraf that it produced — far from lowering costs, the more units of Apligraf that Organogenesis produced, the greater its losses would be.

66. Further, according to several former employees of Organogenesis during the Class Period with knowledge of the relevant facts — a Senior Director (non-Board level), a Project Engineer and a former Materials Handler — Organogenesis would not be reimbursed by Novartis for any units of Apligraf that were manufactured by Organogenesis pursuant to Novartis’ sales forecasts, but that ultimately were not sold by Novartis. Thus, as alleged above, the Company took a “huge loss” every time that Novartis was unable to sell units of the product that Organogenesis had manufactured. The damage to the Company’s bottom line caused by this failure to receive compensation for Apligraf units manufactured but not sold was compounded by the fact that, as alleged above, Novartis’ sales forecasts were “*always inflated*.” Defendants were motivated to and did conceal the true operational and financial condition of Organogenesis, and materially misrepresented and failed to disclose the adverse conditions that were adversely affecting Organogenesis throughout the Class Period, because it enabled the Company, defendants and Company insiders to register for sale and/or sell over 6 million shares of Company stock and/or securities valued at over \$68 million, prior to any disclosure to the market.

67. Indeed, according to the former director (non-Board level) on the senior management team of Organogenesis during the Class Period, several members of the senior management of the Company were more concerned with recouping their own personal investments in the Company than in pursuing the interests of shareholders. According to this

former director, *a culture of “corporate greed” prevailed among the senior management of the Company*, who were primarily interested in “taking care of themselves at the top.” This former director personally attended a meeting of the members of the Company’s board of directors that occurred after Defendant Stein had left the Company, at which defendants Erani as well as other members of the Board, said that *“they needed to get back their investments”* and that, in the words of these board members, they *“were not going to have been taken by Herb Stein.”*

**Defendants’ Materially False and Misleading  
Statements Made During the Class Period**

68. The Class Period begins on November 15, 1999. On that day, Organogenesis published a release on *Business Wire* announcing financial results for the third quarter of 1999, the period ending September 30, 1999. For the third quarter of 1999, Organogenesis reported total revenues of \$946,000, equal to a net loss of \$0.21 per share, compared to a net loss of \$0.25 per share the prior quarter. According to the release, total expenses for the third quarter of 1999 were \$7.426 million, including one-time technology acquisition charges of \$900,000, compared to a sequential loss of \$8.527 million. This release also quoted defendant Stein, as follows:

Apligraf is a revolutionary technology development to provide significant advantages in wound healing. Alpigraf is FDA approved, *well-received by physicians* and can be a highly cost-effective therapy for many patients. The key remaining piece of the puzzle is gaining broad, standardized reimbursement. *Achieving standardized reimbursement for Apligraf is a top priority at both Novartis and Organogenesis and is being addressed aggressively by both companies.*

69. A subsequent release, dated December 2, 1999, reported that Apligraf sales reached a *“record number”* in November 1999 — 755 units. In that release, defendant Tuck — the Company’s Chief Strategic Officer, touted the marketing and sales efforts of Novartis, stating that *“[t]he growth now being seen is due to new Apligraf marketing and sales initiatives by*

*Novartis* and is independent of the efforts underway to gain standardized reimbursement for the product.”

70. **3Q:99 Form 10-Q.** On or about November 15, 1999, the Company filed with the SEC the Company’s financial results for the third quarter of 1999, the period ended September 30, 1999, pursuant to its Form 10-Q signed by defendants Stein and Lopolito. The Company’s Form 10-Q for the third quarter of 1999 stated that “[w]e expect *Apligraf commercial sales to increase.*” [Emphasis added.] The Form 10-Q also stated that:

Production costs exceeded product sales due to the start-up costs of new product introduction and the high costs associated with low volume production. *We expect production volume to increase and our margins to improve.* We expect to continue to *expand manufacturing operations* and advance the product pipeline during the remainder of 1999 and into 2000. [Emphasis added.]

71. Following the publication of the Company’s earnings announcement, the price of Organogenesis rallied — trading from a low of \$6.81 per share on November 15, 1999, to above \$12.30 per share on December 2, 1999.

72. **\$50 Million Shelf-Registration.** Taking full advantage of the artificial inflation in the price of Organogenesis stock caused by the publication of defendants’ false and materially misleading statements, on or about December 27, 1999, defendants raced to the market to register for sale at least \$50 million in mixed securities in a “shelf registration.” The shelf registration would allow the Company to sell up to 3 million shares of common stock either directly or through convertible securities at the sole discretion of the Company. In connection with this shelf registration, the Company filed with the SEC a Registration Statement on December 27, 1999, and two amended Registration Statements, filed on February 3, 2000 and

February 14, 2000, respectively, all of which incorporated by reference the Company's Form 10-Q for the third quarter of 1999.

73. On January 13, 2000, defendant Laughlin presented at the Hambrecht & Quist Annual Healthcare Conference held in San Francisco, California, where he reiterated former guidance and where he further conditioned investors to believe that the Company was operating according to plan. The following day, January 14, 2000, defendant Laughlin also provided a widely circulated interview, with *The Wall Street Transcript*, during which he also represented, in part, that "*we're not concerned that we won't ultimately be successful*," despite the fact that the adoption of Alpigraf had, to that point, "gone slower than we'd like." (Emphasis added)

74. **Amended 3Q:99 Form 10-Q.** On or about February 14, 2000, defendants filed with the SEC the Company's amended financial results for the third quarter of 1999, the period ended September 30, 1999, pursuant to its amended Form 10-Q signed by defendants Laughlin and Lopolito. The Company's amended Form 10-Q for the third quarter of 1999 contained the same materially false and misleading information as had previously been announced on November 15, 1999, in addition to the following:

**Basis of Presentation:**

The accompanying unaudited consolidated financial statements of Organogenesis Inc., have been prepared in accordance with generally accepted accounting principles for interim financial information and with the instructions to Form 10-Q and Article 10 of Regulation.... *In the opinion of management, the accompanying consolidated financial statements include all adjustments, consisting of normal recurring adjustments, necessary for a fair presentation of the financial position, results of operations and changes in cash flows for the periods presented....*[Emphasis added].

75. In addition to the foregoing, Organogenesis' Form 10-Q for the third quarter of 1999 also characterized rising costs during the third quarter as one-time events and predicted that costs would foreseeably remain in line with guidance, as follows:

Production costs exceeded product sales due to the start-up costs of new product introduction and the high costs associated with low volume production. *We expect production volume to increase and our margins to improve.* We expect to continue to *expand manufacturing operations* and advance the product pipeline during the remainder of 1999 and into 2000. [Emphasis added.]

Regarding the \$6.2 million payment for the conversion of the Series C convertible preferred shares, the Form 10-Q reported the existence of this payment, but it did *not* identify the recipients.

76. The statements contained in Organogenesis' November 15, 1999 release, its SEC filings and those statements made by defendants to analysts, investors and the press during the period November 15, 1999 through February 14, 2000 referenced above, were each materially false and misleading when made, and were known by defendants to be false or were recklessly disregarded as such thereby, for the following reasons:

(a) Defendants failed to disclose the material adverse factors affecting the Company alleged in paragraphs 59-67, *supra*.

(b) Contrary to defendants' representations that production volume would increase and that as a consequence of that increase the Company's margins would improve, as confirmed by former employees of Organogenesis, the Company was experiencing serious problems in manufacturing Apligraf and there was "no way" the Company could feasibly mass-produce Apligraf. Further, it was not true that costs exceeded sales due to start-up costs and the high costs of low volume production, and that the Company's margins would improve as production volume increased. As confirmed by former employees of Organogenesis, it was well known by the upper management of the Company that, throughout the Class Period, Organogenesis was losing money on every sale of Apligraf because of the disadvantageous terms of the Novartis marketing agreement — under which Novartis shared revenue from Apligraf

sales that was below the product's manufacturing cost to Organogenesis. Given the terms, and the revised terms, of the Novartis marketing agreement — which caused Organogenesis to lose money on every unit of Apligraf that it produced — *far from lowering costs, the more units of Apligraf that Organogenesis produced, the greater its losses would be.*

(c) Contrary to defendants' representations that Apligraf was "*well-received by physicians*" and that achieving standardized reimbursement for Apligraf was being aggressively addressed by the Company, manufacturing and distribution problems, contamination issues, inadequate marketing support, and difficulties in obtaining reimbursement for Apligraf were causing increasing frustration among physicians, who were becoming less willing to order or re-order Apligraf for their patients. Continuing difficulties in obtaining reimbursement for Apligraf were not being adequately addressed by either Organogenesis or Novartis, which adversely affected Apligraf's future sales prospects.

(d) Defendants' public statements touting the "record number" of sales in November 1999 and Novartis' "new Apligraf marketing and sales initiatives" were materially misleading and incomplete given that, as confirmed by several former employees of Organogenesis, the Company was experiencing serious manufacturing and marketing problems that were inhibiting sales and damaging future sales development prospects. Further, as defendants knew but did not disclose, Novartis' marketing team did not have the proper training experience or expertise in selling a product like Apligraf, with the result that Novartis' efforts to market Apligraf suffered significantly.

(e) Defendants' representations that they expected Apligraf "commercial sales to increase" was untrue given the marketing problems that Novartis was experiencing because of inadequate marketing support and the problems with the manufacturing and distribution of



Apligraf that were causing frustration among purchasers, leading to reluctance among physicians to order or re-order Apligraf.

(f) Contrary to defendants' representations that they were "not concerned that we won't ultimately be successful," defendants knew that the Company's ultimate prospects for achieving profitability were severely compromised by the fundamental problems alleged in paragraphs 59-67, *supra*, including the Company's serious manufacturing and marketing problems, its inability to access as necessary adequate funding to keep the Company viable, the difficulties in achieving reimbursement for Apligraf, and the disruptive effect on operations that high turnover and infighting among the Company's senior management was having and would continue to have for the foreseeable future.

(g) Contrary to defendants' representations, the Company's amended Form 10-Q for the third quarter of 1999 did not reflect the true financial condition of the Company because it failed to disclose the adverse factors affecting the Company's operations and future viability alleged in subparagraphs (a) through (f) above and in paragraphs 59-67, *supra*.

77. **\$9.4 Million Equity Sale.** One month later, on February 24, 2000, with Organogenesis stock trading at almost \$15.50 per share, defendants issued a release announcing that Organogenesis had completed the sale of over 688,000 shares of common stock for gross proceeds of \$9.4 million. According to defendants, this was a remarkable accomplishment given that it allowed them to raise *more money than defendants had originally planned* — and presumably placed Organogenesis in a position of having *more money than needed to fulfill defendants' near-term objectives*. According to the Company's release, defendants' purported "goal" had been to raise \$6.2 million but the offering priced at \$14 per share was over-



subscribed due to the “strong interest in our Company.” This placement raised the total number of Organogenesis shares outstanding to 31.3 million from 30.6 million.

78. At the time of this offering, the Company stated that proceeds from the sale of these shares would enable, among other things, the retirement of \$6.2 million in preferred stock. Defendants created the impression that the redemption of Organogenesis’ preferred stock was necessary to bolster the Company’s debt and equity ratings. The Company’s February 24, 2000 release quoted defendant Tuck, who exhibited a complete knowledge of Organogenesis’ financial and operational performance, stating that, *“The completion of this initial shelf-offering removes any concern among the investment community about the retirement of our \$6.2 million of preferred stock.”* No disclosure was made as to the identity of the owners of these retired preferred shares.

79. Moreover, the following day, February 25, 2000, the Company also issued a release announcing that defendants had raised an additional \$1.4 million through the sale of an additional 100,000 shares to satisfy an additional over-subscription commitment. This sale brought the total February 2000 Offering proceeds to over \$10.8 million, and the total number of shares issued and outstanding to 31.4 million.

80. **\$16 Million In Equity Sales.** Taking further advantage of the artificial inflation in the price of Organogenesis stock defendants’ misrepresentations and omissions had caused, on March 9, 2000, *defendants sold another 300,000 shares of Organogenesis common stock at approximately \$17.60 per share* in a private-placement, thereby realizing another \$5.27 million. Including this latest offering, the Company had issued a total of 1.088 million shares in less than 20 days in combined placements valued at over \$16 million.

81. On March 7, 2000, shares of the Company rallied to a Class Period high of over \$22.37 per share on substantial volume of over 1.5 million shares, driven by management's optimistic guidance, and the false and misleading assurances that the Company was operating according to plan — capable of achieving profitability in the near-term — and that the Company had raised enough money to fund operations. Within days, however, on March 13, 2000, defendant Stein suddenly and unexpectedly announced that he was resigning from the Board of the Company. Stein had only accepted the position of Chairman Emeritus of the Board in January 2000, after resigning as Chairman and Chief Executive Officer effective January 1, 2000. At the time of his resignation, no disclosure was made regarding the Company's inability to generate sufficient funds from operations or sources of debt or equity to allow Organogenesis to achieve profitability, or to foreseeably remain as a viable business.

82. On or about March 21, 2000, as President and CEO of Organogenesis, defendant Laughlin showcased a presentation of the Company at the New York Society of Securities Analysts 4<sup>th</sup> Annual Health Care Conference, held in New York City.

83. **\$6.2 Million Series C Redemption.** Consistent with defendants' earlier announcement, on March 27, 2000, Organogenesis issued a release which reported that defendants had opted to use at least \$6.2 million of its recently raised cash to pay for the redemption of the Company's outstanding Series C convertible preferred stock. According to the Company's release, the Series C convertible stock had a mandatory conversion date of March 26, 2000, but these shares were redeemable in either common stock or cash, at the option of Organogenesis. The Company's release did not reveal why the cash election was chosen by Organogenesis or who received the cash payments as a result of this redemption.

84. **4Q and FY:99 Results.** On March 31, 2000, Organogenesis issued a release published on *Business Wire* which purported to announce financial results for the fourth quarter and year end 1999. According to the Company, results for the fourth quarter and full year 1999 were *“consistent with the transition in progress from a research focused company to a research based operating company with a novel medical product in introduction phase,”* in addition to stating the following:

For the year ended December 31, 1999, revenue from product sales to related party and others was \$1.8 million, compared with \$1.1 million in 1998. Total revenues were \$3.6 million for 1999, compared with \$9.0 million in 1998, which included \$6.8 million in milestone payments from Novartis Pharma AG. Total expenses (including manufacturing, research and development, and general and administrative costs) were \$31.9 million in 1999, compared with \$23.0 million in 1998. Net loss was \$0.93 per share (or \$28.4 million) for 1999 compared with a net loss of \$0.48 per share (or \$14.0 million) for 1998.

The *increase in expenses was primarily due to: strengthening our employee base* through additions to our production, research and support teams; costs to support publication studies and other sponsored programs, as well as *increased activities in our corporate communications and business development functions*; interest expense on the convertible debt issued last March; *expanding our production and warehouse capacity* while consolidating our administrative space; and the acquisition of intellectual property and assets from Baxter Healthcare Corporation. [Emphasis added.]

In addition to the foregoing, defendant Laughlin also used this release to condition investors to believe that the Company was operating according to plan and was actually taking steps to *reduce* operating costs, as follows:

Prior to the US commercialization of Apligraf, our corporate focus needed to be on supporting the validity of the product concept through solid research, clinical trials and manufacturing consistency.... *Now, as sales of Apligraf begin to develop, our focus must include driving down per unit manufacturing costs through the development and implementation of more efficient methods of production.* At the same time, we are continuing to support other programs in our pipeline — the VITRIX(TM) living soft tissue replacement product, the vascular graft, the liver assist device — important to our longer term growth. [Emphasis added.]

85. **FY:99 Form 10-K.** The same day, March 31, 2000, Organogenesis also filed with the SEC its financial results for full year 1999, pursuant to a Form 10-K signed by defendants Laughlin, Erani and Lopolito, among others. In addition to repeating many of the same misrepresentations made in the Company's release, the 1999 Form 10-K also stated that, Organogenesis "*believe[s] that future capital comprised of product sales, research and development support payments and debt equity financings will be sufficient to fund future operations into 2001 . . . .*" The Form 10-K also represented that its marketing partner, Novartis, had "*a marketing and sales force[] with technical expertise and distribution capability*" and that "*[w]e expect Apligraf commercial sales to continue to increase.*" The Form 10-K further stated that:

Cost of product sales exceeded product sales due to the start-up costs of new product introduction and the high costs associated with low volume production. *We expect production volume to increase and our margins to improve. We expect to continue to expand production operations during the next 12 months.*

\* \* \*

We expect production costs to exceed product sales for the near term due to start-up expenses and the high costs associated with low volume production. However, *we expect production volume to increase.*

86. Following the filing of Organogenesis' 2000 Form 10-K, shares of the Company traded as high as \$12.60 per share on March 31, 2000.

87. The statements made by defendants and contained in the Company's March 31, 2000 release and 1999 Form 10-K, reproduced herein *supra*, were each materially false and misleading and were known by defendants to be false at that time, or were recklessly disregarded as such for the following reasons:

(a) Defendants failed to disclose the material adverse factors affecting the Company alleged in paragraphs 59-67, *supra*.

(b) Contrary to defendants' representation that Novartis had "*a marketing and sales force[] with technical expertise and distribution capability*," Novartis' marketing team did not have the proper training, experience or expertise in selling a product like Apligraf, with the result that Novartis' efforts to market Apligraf suffered significantly. In fact, as alleged above, according to former employees of Novartis and Organogenesis, Novartis "*had no idea what they were doing*" when it came to marketing a living-tissue product like Apligraf.

(c) Contrary to defendants' suggestion, the Company's planned focus on "driving down per unit manufacturing costs" and implementing "more efficient methods of production" would not achieve profitability for the Company. As defendants were well aware at the time but failed to disclose, and as confirmed by former employees of Organogenesis, Organogenesis was losing money on every unit of Apligraf that it produced because of the terms of the disadvantageous terms of the Novartis marketing agreement — under which Novartis shared revenue from Apligraf sales that was well below the product's manufacturing cost to Organogenesis and reimbursed Organogenesis for production costs in connection with unsold units at only a fraction of the actual costs of production.

(d) Defendants' representation that they expected Apligraf "commercial sales to increase" was untrue given the marketing problems that Novartis was experiencing because of inadequate marketing support and the significant problems with the manufacturing and distribution of Apligraf that were causing frustration among purchasers, leading to reluctance among physicians to order or re-order Apligraf and damaging Apligraf's future sales development prospects.

(e) Contrary to defendants' representations that production volume would increase and that as a consequence of that increase the Company's margins would improve, as

confirmed by former employees of Organogenesis, the Company was experiencing serious problems in manufacturing Apligraf and there was “no way” the Company could feasibly mass-produce Apligraf. Further, it was not true that costs exceeded sales due to start-up costs and the high costs of low volume production, and that the Company’s margins would improve as production volume increased. As confirmed by former employees of Organogenesis, it was well known by the upper management of the Company that, throughout the Class Period, Organogenesis was losing money on every sale of Apligraf because of the disadvantageous terms of the Novartis marketing agreement — under which Novartis shared revenue from Apligraf sales that was well below the product’s manufacturing cost to Organogenesis. Given the terms, and the revised terms, of the Novartis marketing agreement — which caused Organogenesis to lose money on every unit of Apligraf that it produced — *far from lowering costs, the more units of Apligraf that Organogenesis produced, the greater its losses would be.*

(f) Defendants’ representations touting the oversubscription of the Company’s stock offering as a result of investors’ “strong interest in the Company” were materially misleading and incomplete given that defendants failed to disclose the obstacles that existed in accessing essential future funding. Defendants’ representations misleadingly conditioned investors to believe that the Company would be able to raise the additional equity and debt financing necessary to keep the Company operational and achieve profitability. As later revealed, the Company in fact did not have access to such funding.

(g) Contrary to defendants’ representations that they expected to “continue to expand production operations,” according to former employees of the Company, Organogenesis was experiencing serious problems in manufacturing Apligraf and there was “no way” the

Company could feasibly mass-produce Apligraf given the Company's inadequate production infrastructure and processes.

88. **Stein Stock Registration.** Taking further advantage of the artificial inflation in the price of Organogenesis that defendants' false statements had caused, on or about April 21, 2000, defendant Stein caused the Company to file with the SEC a Registration Statement allowing him to register for sale over 732,000 shares of his personally held Organogenesis stock. The Registration Statement, signed by defendants Laughlin, Lopolito and Erani, among others, stated in part the following:

#### CALCULATION OF REGISTRATION FEE

Title of securities to be registered	Amount to be registered(1)	Proposed maximum offering price per share(2)	Proposed maximum aggregate offering price(2)	Amount of registration fee
Common Stock, \$.01 par value (3)	732,423	\$9.4375	\$6,912,242.10	\$1,824.83

\* \* \*

This Prospectus is part of a Registration Statement we filed with the Securities and Exchange Commission for registration of up to 732,423 shares of Common Stock for sale by the selling stockholder listed on page 12 of this prospectus.

Each of the shares to be sold either were issued upon the exercise of options held by the selling stockholder. The selling stockholder may offer his common stock through transactions on the American Stock Exchange; in private transactions at current market prices; or at negotiated prices.

We will not receive any of the proceeds from the selling stockholder's sale of his common stock.

\* \* \*

#### USE OF PROCEEDS

We will receive no net proceeds from the sale of the common stock. *All proceeds will be realized by the selling stockholder.*



**SELLING STOCKHOLDER**

The selling stockholder, Herbert M. Stein, is offering shares which have been acquired by him upon the exercise of options granted under a stock option grant. Mr. Stein previously served as Chairman and Chief Executive Officer of the Company until his retirement on December 31, 1999 and as a member of the Board of Directors of the Company until March 17, 2000. The following table lists the selling stockholder and other information regarding beneficial ownership of the common stock by the selling stockholder as of March 29, 2000:

<b>Name</b> -----	<b>Number of Shares Beneficially Owned Prior to the Offering</b> -----	<b>Number of Shares Being Offered</b> -----	<b>Number of Shares Beneficially Owned After Offering</b> -----	<b>Percentage of Class to be Beneficially Owned After Offering</b> -----
Herbert M. Stein	2,086,597	723,423	1,363,174	4.0%

This registration represented almost half of defendant Stein's personal holdings (excluding approximately 1.1 million shares of common stock held by H.M. Stein Associates to which defendant Stein disclaimed beneficial ownership).

89. **1Q:00 Results.** On May 11, 2000, Organogenesis issued a release published on *Business Wire* which purported to announce financial results for the first quarter of 2000. Defendants again stated that the Company's quarterly results were "consistent with the Company's ongoing transition from being a research company to being a research-based operating company," in addition to stating the following:

Revenue from product sales to related party and others were \$646,000 for the first quarter of 2000 compared with \$543,000 for the fourth quarter of 1999. The growth in product revenue was due to increased sales of Apligraf(R) to Novartis. Total revenues were \$1,084,000 for the first quarter of 2000 compared with \$1,015,000 for the fourth quarter of 1999. Total costs and expenses were \$7,770,000 for the first quarter of 2000 compared with \$9,368,000 for the fourth quarter of 1999, which had



included disproportionately higher occupancy and financing costs. Net loss was \$0.21 per share (or \$6,686,000) for the first quarter of 2000 compared with \$0.27 per share (or \$8,353,000) for the fourth quarter of 1999.

The first quarter of 2000 product revenues of \$646,000 compare with \$318,000 for the first quarter of 1999. The total revenues of \$1,084,000 compare with \$679,000 for the same quarter in 1999 and the total costs and expenses of \$7,770,000 compare with \$6,605,000 for the same quarter in 1999. The net loss of \$0.21 per share (or \$6,686,000) compares with a net loss of \$0.19 per share (or \$5,926,000) for the same quarter in 1999.

This release also quoted defendant Laughlin, as follows:

***Key to Apligraf sales development are two factors: obtaining approval for diabetic foot ulcers and gaining standardized Apligraf reimbursement...***

The Advisory Panel's recommendation earlier this week is a key achievement towards the diabetic foot ulcer indication. We are equally committed to gaining standardized reimbursement for Apligraf. [Emphasis added.]

90. **1Q:00 Form 10-Q.** On or about May 15, 2000, defendants filed with the SEC the Company's financial results for the first quarter of 2000, the period ended March 31, 2000, pursuant to a Form 10-Q, signed by defendants Laughlin and Arcari. The Company's first quarter 2000 Form 10-Q contained the same materially false and misleading financial information as had previously been announced on May 11, 2000, in addition to reporting, in part, the following:

#### Basis of Presentation

-----

The accompanying unaudited consolidated financial statements of Organogenesis Inc. have been prepared in accordance with generally accepted accounting principles for interim financial information and with the instructions to Form 10-Q and Article 10 of Regulation S-X.... ***In the opinion of management, the accompanying consolidated financial statements include all adjustments, consisting of normal recurring adjustments, necessary for a fair presentation of the financial position, results of operations and changes in cash flows for the periods presented....***

\* \* \*

#### Costs and Expenses

Cost of product sales: Cost of product sales was \$1,191,000 for the three months ended March 31, 2000, compared to \$603,000 for the same period in 1999, due to increased unit sales of Apligraf to Novartis. Cost of product sales includes the direct costs to manufacture and package Apligraf and an allocation of our production related indirect costs. ***Cost of product sales exceeded product sales due to the start-up costs of new product introduction and the high costs associated with low volume production. We expect production volume to increase and our margins to improve. We expect to continue to expand production operations during 2000.*** [Emphasis added.]

91. The statements made by defendants and contained in the Company's May 11, 2000 release and first quarter 2000 Form 10-Q, reproduced herein, *supra*, were each materially false and misleading and were known by defendants to be false at that time, or were recklessly disregarded as such for the following reasons:

(a) Defendants failed to disclose the material adverse factors affecting the Company alleged in paragraphs 59-67, *supra*.

(b) It was not true that "[k]ey to Apligraf sales development are two factors: obtaining approval for diabetic foot ulcers and gaining standardized Apligraf reimbursement." Defendants were aware, but did not disclose, that sales of Apligraf and future sales development prospects were hampered by serious manufacturing and marketing problems, including the Company's inability to mass produce Apligraf, Novartis' lack of training, experience and expertise in marketing Apligraf and increasing physician resistance to the product.

(c) Contrary to defendants' representations that production volume would increase and that as a consequence of that increase the Company's margins would improve, as confirmed by former employees of Organogenesis, the Company was experiencing serious problems in manufacturing Apligraf and there was "no way" the Company could feasibly mass-produce Apligraf. Further, it was not true that costs exceeded sales due to start-up costs and the high costs of low volume production, and that the Company's margins would improve as

production volume increased. As confirmed by former employees of Organogenesis, it was well known by the upper management of the Company that, throughout the Class Period, Organogenesis was losing money on every sale of Apligraf because of the disadvantageous terms of the Novartis marketing agreement — under which Novartis shared revenue from Apligraf sales that was well below the product's manufacturing cost to Organogenesis. Given the terms, and the revised terms, of the Novartis marketing agreement — which caused Organogenesis to lose money on every unit of Apligraf that it produced — *far from lowering costs, the more units of Apligraf that Organogenesis produced, the greater its losses would be.*

(d) Contrary to defendants' representations that they expected to "continue to expand production operations," the Company was experiencing serious problems in manufacturing Apligraf and, according to a former employee of Organogenesis, there was "no way" the Company could feasibly mass-produce Apligraf given the Company's inadequate production infrastructure and processes.

(e) Contrary to defendants' representations, the Company's first quarter 2000 Form 10-Q did not reflect the true financial condition of the Company because it failed to disclose the adverse factors affecting the Company's operations and future viability alleged in subparagraphs (a) through (d) above and in paragraphs 59-67, *supra*.

92. On or about June 14, 2000, as President and Chief Executive Officer of Organogenesis, defendant Laughlin showcased a very positive presentation of the Company at the Annual Sachs Healthcare Conference in Laguna Niguel, CA.

93. On June 20, 2000, Organogenesis issued a release which announced that the FDA had given final approval of Apligraf treatment for diabetic foot ulcers in addition to its previous indication of venous leg ulcers. While no changes had been made to Apligraf for this market

application, the FDA indication purportedly allowed Organogenesis to expand its market base to include this second group of foot ulcer sufferers. On this news, Organogenesis stock traded as high as \$12.75 per share in intra-day trading.

94. **Laughlin on CNBC Power Lunch.** On June 25, 2000, defendant Laughlin appeared on the widely disseminated cable financial news show “Power Lunch,” on the CNBC network. When asked by the CNBC interviewer whether Organogenesis had the ability to obtain profitability through sales of the Company’s only product Apligraf, defendant Laughlin responded, by stating that Organogenesis *“can become profitable and will become profitable with Apligraf alone. The two main drivers of that are diabetic foot ulcer approval which happened last week and getting that standardized Medicare reimbursement, which has been slow going. We’re optimistic....”* [Emphasis added.]

95. **Apligraf Sales 7/00.** On August 2, 2000, Organogenesis issued a release which purported to announce Apligraf sales for the month of July 2000. This release stated that the month “held notable achievements significant to future sales development.” Despite this statement, sales of Apligraf had declined substantially from the prior month, reaching only 912 units in July. Defendant Laughlin, however, suggested that the decline in sales was the result of the “summer vacation period” — not that they were the result of any production problems within the Company or any issues with product quality, product acceptance or Novartis’ marketing.

96. **2Q:00 Results.** On August 14, 2000, Organogenesis issued a release published on *Business Wire* which purported to announce financial results for the second quarter 2000. This quarter defendants stated that the Company was “in the process of transitioning from being a research company to becoming an operating company with a strong research base,” in addition to stating the following:

For the second quarter of 2000, total revenues were \$6.4 million compared with \$0.9 million for the same quarter in 1999. The 2000 revenues include a \$5 million milestone payment from Novartis that was received in March and earned in June with the approval of Apligraf for diabetic foot ulcers. Total costs and expenses were \$8.5 million during the second quarters of both 2000 and 1999. The 1999 expenses included a non-cash charge of \$0.9 million for a technology-related acquisition, while the 2000 expenses show modest increases across each expense category. Net loss was \$2.0 million (\$0.06 per share), compared with a net loss of \$7.6 million (\$0.25 per share) for the same quarter in 1999.

The Company reportedly had \$22.3 million in cash, cash equivalents and investments at June 30, 2000.

97. In addition to reporting the following, the August 14, 2000 release was also used by defendant Laughlin to condition investors to believe that Organogenesis had achieved certain milestones such that it was foreseeable that the Company could achieve profitability in the near-term. In this regard, defendant Laughlin was quoted in the August 14, 2000 release, as follows:

When we announced our first quarter results three months ago, we stated our commitment to achieving *two important drivers of Apligraf sales: FDA approval for diabetic foot ulcers and Medicare reimbursement for the product's cost. We now have tangible achievements in both areas.* Apligraf was approved for diabetic foot ulcers in June and its marketing was launched by Novartis in July. Effective this month, Apligraf qualifies for Medicare reimbursement when used in the hospital outpatient setting, such as a hospital-affiliated wound care center. There has also been progress in gaining Medicare reimbursement for Apligraf applied in the doctor's office, with additional activities underway. [Emphasis added.]

Defendant Laughlin also claimed that the Company had "*further strengthened its manufacturing and management team*" with the addition of a new Vice President of Operations in June 2000.

98. **2Q:00 Form 10-Q.** The same day, August 14, 2000, defendants also filed with the SEC the Company's financial results for the second quarter of 2000, the period ended June 30, 2000, pursuant to a Form 10-Q signed by defendants Laughlin and Arcari. The Company's

second quarter 2000 Form 10-Q contained the same materially false and misleading financial information as had been previously announced, in addition to reporting, in part, the following:

Basis of Presentation

-----

The accompanying unaudited consolidated financial statements of Organogenesis Inc. have been prepared in accordance with generally accepted accounting principles for interim financial information and with the instructions to Form 10-Q and Article 10 of Regulation S-X.... *In the opinion of management, the accompanying consolidated financial statements include all adjustments, consisting of normal recurring adjustments, necessary for a fair presentation of the financial position, results of operations and changes in cash flows for the periods presented...*

\* \* \*

COSTS AND EXPENSES

Cost of product sales: Cost of product sales was \$1,243,000 and \$2,434,000 for the three and six months ended June 30, 2000, compared to \$1,126,000 and \$1,730,000 for the same periods in 1999, due to increased unit sales of Apligraf to Novartis. Cost of product sales includes the direct costs to manufacture and package Apligraf and an allocation of our production related indirect costs. *Cost of product sales continues to exceed product sales due to the high costs associated with low volume production. We expect production volume to increase and our margins to improve. We expect to continue to expand production operations during 2000.* [Emphasis added.]

99. **Apligraf Sales 3Q:00.** On October 3, 2000, defendants published a release on *Business Wire* which reported record Apligraf sales for September and the third quarter of 2000—1081 units in September 2000 and a total of 3,232 units during the third quarter of 2000. In addition to reporting the foregoing, this release also quoted defendant Laughlin who stated that, *“[t]hird quarter Apligraf achievements . . . laid an important foundation for future sales development.”* [Emphasis added.]

100. The statements made by defendant Laughlin during the June 25, 2000 CNBC interview and other statements made by defendants and contained in the Company’s August 2,

2000 release and Form 10-Q for the second quarter of 2000, reproduced herein, *supra*, were each materially false and misleading and were known by defendants to be false at that time, or were recklessly disregarded as such for the following reasons:

(a) Defendants failed to disclose the material adverse factors affecting the Company alleged in paragraphs 59-67, *supra*.

(b) Contrary to defendants' representation, it was not true that the Company could "become profitable and *will become profitable* with Apligraf alone" and that "the two main drivers" of profitability would be the approval of Apligraf for diabetic foot ulcer approval and the receipt of standardized Medicare reimbursement. As defendants were aware, the disadvantageous terms of the Novartis marketing agreement — under which Organogenesis was losing, and would continue to lose, money on every unit of Apligraf that it produced — ensured that the Company could not achieve profitability through the production and sale of Apligraf. Further, as alleged in paragraphs 59-67, *supra*, the Company was suffering from a host of undisclosed financing, manufacturing, marketing and management problems that were obstacles to the Company's achievement of its purported plan for profitability.

(c) For the same reasons stated in subparagraph (b) above, defendants' statements that "the two important drivers of Apligraf sales" were obtaining approval for diabetic foot ulcers and gaining standardized Apligraf reimbursement misled investors into believing that these were the last two pieces of the sales puzzle, and that given that the Company had now achieved "tangible achievements in both areas," sales were poised to increase, allowing the Company to achieve profitability. Defendants were aware, but did not disclose, that sales of Apligraf and future sales development prospects were hampered by serious manufacturing and marketing problems, including the Company's inability to mass produce Apligraf, Novartis' lack



of training, experience and expertise in marketing Apligraf and increasing physician resistance to the product.

(d) Contrary to defendants' representations that they expected to "continue to expand production operations," the Company was experiencing serious problems in manufacturing Apligraf and there was "no way" the Company could feasibly mass-produce Apligraf given the Company's inadequate production infrastructure and processes.

(e) Defendants' representation that the Company had made "notable achievements significant to future sales development" in July 2001 despite declining sales volume, and their suggestion that the decline was the result of the "summer vacation period" was materially misleading and incomplete given that the Company's sales were adversely affected by the significant manufacturing and marketing problems, including problems with product quality, product acceptance and Novartis' marketing, and that these problems were actually exacerbating, rather than improving, "future sales development."

(f) Contrary to defendants' representation that they had "further strengthened" the Company's "manufacturing and management team," recent turnover among the Company's senior management and directors, including the departure of defendant Stein and others, as well as infighting among senior management, were weakening the Company's management team and adversely affecting the Company's operations.

(g) Contrary to defendants' representations that production volume would increase and that as a consequence of that increase the Company's margins would improve, as confirmed by former employees of Organogenesis, the Company was experiencing serious problems in manufacturing Apligraf and there was "no way" the Company could feasibly mass-produce Apligraf. Further, it was not true that costs exceeded sales due to start-up costs and the



high costs of low volume production, and that the Company's margins would improve as production volume increased. As confirmed by former employees of Organogenesis, it was well known by the upper management of the Company that, throughout the Class Period, Organogenesis was losing money on every sale of Apligraf because of the disadvantageous terms of the Novartis marketing agreement — under which Novartis shared revenue from Apligraf sales that was well below the product's manufacturing cost to Organogenesis. Given the terms, and the revised terms, of the Novartis marketing agreement — which caused Organogenesis to lose money on every unit of Apligraf that it produced — *far from lowering costs, the more units of Apligraf that Organogenesis produced, the greater its losses would be.*

(h) Defendants' representation that they had established an "important foundation for future sales development" was materially misleading and incomplete given that defendants failed to disclose the fundamental manufacturing, marketing and management problems alleged above, which had actually established a weakened foundation for developing future sales.

(i) Contrary to defendants' representations, the Company's second quarter 2000 Form 10-Q did not reflect the true financial condition of the Company because it failed to disclose the adverse factors affecting the Company's operations and future viability alleged in subparagraphs (a) through (h) above and in paragraphs 59-67, *supra*.

101. **3Q:00 Results.** On November 14, 2000, Organogenesis issued a release published on *Business Wire* which purported to announce financial results for the third quarter 2000. Again, defendants heralded the achievements of Apligraf, reporting that Organogenesis was still "in the process of transitioning from being a research Company to becoming an operating Company with a strong research base." This release also stated, in part, the following:

For the three months ended September 30, 2000, total revenues were \$1.4 million compared with \$0.9 million for the same quarter in 1999. The increase was due to increased product sales to related party and others and increased income from grants and interest. Total costs and expenses were \$8.3 million during the third quarter of 2000 compared with \$7.4 million for the same quarter in 1999. The increase was due to increased cost of product sales, research and development expenses, interest expense and general and administrative expenses. Net loss was \$6.9 million (\$0.20 per share), compared with a net loss of \$6.5 million (\$0.21 per share) for the same quarter in 1999.

In addition to the foregoing, defendant Laughlin was also quoted in this release as conditioning investors to believe the following:

This summer we made important progress in several areas central to Apligraf sales development. Apligraf was approved and launched for diabetic foot ulcers, qualified for Medicare reimbursement when used in the hospital outpatient setting and marketer Novartis expanded the field force selling the product. We believe the Apligraf sales growth seen in the third quarter is the beginning of the effect of these achievements on sales development. *While unit volumes are still small, which adversely affects our cost of production, the trend is encouraging.*

102. **3Q:00 Form 10-Q.** The same day, November 14, 2000, defendants also filed with the SEC pursuant to Form 10-Q the Company's financial results for the third quarter of 2000, the period ended September 30, 2000, signed by defendants Laughlin and Arcari. The Company's Form 10-Q for the third quarter of 2000 contained the same materially false and misleading financial information as had previously been announced, in addition to reporting, in part, the following:

Basis of Presentation

-----

The accompanying unaudited consolidated financial statements of Organogenesis Inc. have been prepared in accordance with generally accepted accounting principles for interim financial information and with the instructions to Form 10-Q and Article 10 of Regulation S-X.... *In the opinion of management, the accompanying consolidated financial statements include all adjustments, consisting of normal recurring adjustments, necessary for a fair presentation of the financial position,*

*results of operations and changes in cash flows for the periods presented....*

\* \* \*

#### COSTS AND EXPENSES

Cost of product sales: Cost of product sales was \$1,310,000 and \$3,744,000 for the three and nine months ended September 30, 2000, compared to \$969,000 and \$2,699,000 for the same periods in 1999, due to increased unit sales of Apligraf to Novartis. Cost of product sales includes the direct costs to manufacture and package Apligraf and an allocation of our production related indirect costs. *Cost of product sales continues to exceed product sales due to the high costs associated with low volume production. We expect production volume to increase and our margins to improve.* [Emphasis added.]

103. **Apligraf Sales 11/00.** Later, on December 4, 2000, Organogenesis announced that November sales of Apligraf were 1488 units — a new record monthly high. In addition, this release again quoted defendant Laughlin who stated that, “[w]e are clearly beginning to see acceleration in the growth of Apligraf sales. October and November establish a new, *higher sales base on which to build*. While it is difficult to predict how the December holidays will impact sales, *we expect to begin seeing in the first quarter the impact of the additional sales representatives that started this past summer.*” [Emphasis added.]

104. The statements made by defendants and contained in the Company’s October 3, 2000 and November 14, 2000 releases and in the Form 10-Q for the third quarter of 2000, reproduced herein, *supra*, were each materially false and misleading and were known by defendants to be false at that time, or were recklessly disregarded as such for the following reasons:

(a) Defendants failed to disclose the material adverse factors affecting the Company alleged in paragraphs 59-67, *supra*.

(b) Contrary to defendants' representations that the "trend" with respect to its ability to increase unit volumes and thus favorably affect the cost of production was "encouraging," as confirmed by former employees of the Company, Organogenesis was experiencing substantial manufacturing problems, which were retarding and hindering the expansion of production scale. Further, defendants were aware but failed to disclose that the most important factor affecting cost of production was not "unit volumes," but rather the unfavorable terms of the Novartis marketing agreement, under which Organogenesis was reimbursed for only a fraction of production costs in connection with units *not* sold, and received a share of revenue on units that *were* sold that was far below cost.

(c) Contrary to defendants' representations that production volume would increase and that as a consequence of that increase the Company's margins would improve, as confirmed by former employees of Organogenesis, the Company was experiencing serious problems in manufacturing Apligraf and there was "no way" the Company could feasibly mass-produce Apligraf. Further, it was not true that costs exceeded sales due to start-up costs and the high costs of low volume production, and that the Company's margins would improve as production volume increased. As confirmed by former employees of Organogenesis, it was well known by the upper management of the Company that, throughout the Class Period, Organogenesis was losing money on every sale of Apligraf because of the disadvantageous terms of the Novartis marketing agreement — under which Novartis shared revenue from Apligraf sales that were well below the product's manufacturing cost. Given the terms, and the revised terms, of the Novartis marketing agreement — which caused Organogenesis to lose money on every unit of Apligraf that it produced — *far from lowering costs, the more units of Apligraf that Organogenesis produced, the greater its losses would be.*

(d) Defendants' public statements touting the "record number" of sales in November 1999, the fact that recent sales established a "higher sales base on which to build" and that the Company expected to see "the impact of the additional sales representatives" in the first quarter of 2001 was materially misleading and incomplete given that, as confirmed by several former employees of Organogenesis, the Company was experiencing serious manufacturing and marketing problems that were inhibiting sales and damaging future sales development prospects. Further, as defendants knew, Novartis' marketing team did not have the proper training, experience or expertise in selling a product like Apligraf, with the result that Novartis' efforts to market Apligraf were suffering significantly.

(e) Contrary to defendants' representations, the Company's Form 10-Q for the third quarter of 2000 did not reflect the true financial condition of the Company because it failed to disclose the adverse factors affecting the Company's operations and future viability alleged in subparagraphs (a) through (d) above and in paragraphs 59-67, *supra*.

105. **500,000 Share Repurchase.** On December 6, 2000, defendants issued a release which announced that the Board of the Company had authorized the repurchase of up to 500,000 shares of Organogenesis common stock — "at the discretion of management." According to defendant Laughlin, the decision to purchase the Company's stock was made by the Board because, "[o]ur Board is sensitive to shareholder dilution and *views current market conditions as an opportunity to purchase shares that the Company considers to be undervalued in view of our prospects.*" [Emphasis added.] In addition, defendant Laughlin also stated that, "the decision to authorize a stock buyback program demonstrates the confidence our Board has in the Company's future." At the time of this announcement, shares of the Company were trading at approximately \$7.50 per share.

106. **Apligraf Sales January 2001.** On February 5, 2001, Organogenesis announced that Apligraf sales had reached another record in January 2001, with 1771 units sold during that period. In addition, this release again quoted defendant Arcari who stated that, “[w]e are pleased with the acceleration being seen in Apligraf sales growth.”

107. **Laughlin on CNBC Power Lunch February 27, 2001.** On February 26, 2001, Organogenesis issued a release which announced the broadening of its 1996 marketing agreement with Novartis Pharma AG — an agreement which purportedly gave Organogenesis the right for three years to sell Novartis up to \$20 million in equity. Under the purported terms of this deal, Organogenesis would also receive funding from Novartis to upgrade the Company’s manufacturing plants and equipment. The following day, February 27, 2001, defendant Laughlin again appeared on nationally televised cable news show CNBC Power Lunch, during which he was interviewed by Bill Griffeth, and stated, the following:

GRIFFETH: What kind of an increase in revenue do you expect from this expansion of the deal with Novartis?

LAUGHLIN: Let me just run through the deal. And you are right, *it is a turning point for us. It is a major improvement in our economic situation.* Unfortunately, I can’t give you the precise details of the deal but let me --

LAUGHLIN: [L]et me tell you the major elements of what it is. We have granted Novartis the rights to two additional living tissue products, one that will be entering clinical trials in the next 30 to 60 days and one that is in research. In exchange for that, *we will receive a substantial increase in the percentage of the revenue* for our living tissue product, which is actually on the market today, called Apligraf. *We will also receive funding for a number of different areas which will enable us to expand our business, get into additional markets and drive down our costs.* We also received a \$20 million stock put. *So any time during the next three years we are able at our discretion and our option to sell Novartis \$20 million of shares.* We may or may not do that, but *it is wonderful safety net to have in our pocket.*

GRIFFETH: Right. Now, as far as the product agreement goes, though, I know you are meeting with Wall Street analysts to talk about this. Are you raising guidance, though, as far as revenue for this year as a result of this?

LAUGHLIN: What we are doing and the thing people have been most interested in is giving them guidance on our profitability. *What we now feel with the increased revenue, with the funding support that we will get, we are now targeting to pass through break even and reach profitability in the second quarter of next year — sorry, the third quarter of next year.*

GRIFFETH: Third quarter of next year. OK. And as a result of this, I am curious, I mean are you finding or at least receiving approval for new applications for Apligraf? I am wondering why Novartis is doing this now. I know I should ask them but maybe you can provide some guidance on that.

LAUGHLIN: I think *they are truly convinced that there is major business here. ....Everything is coming together. I think they are saying, yes, this is working. This is going to be a very big business. Let's get into it deeper. Let's commit to the business.*

\* \* \*

**GRIFFETH:** Now and you factor, when you provide this guidance for break even, is that a part of that guidance of the anticipated approval of those products and when they might be available for market?

LAUGHLIN: *As we look into the things that go into our break even we are targeting to reach break even with or without those approvals.* One thing that we will hit before break even is we hope to be approved for launch into the European market in approximately the second quarter of next year. [Emphasis added.]

At the time of this interview shares of Organogenesis traded at above \$12.00.

108. The statements made by defendant Laughlin during the February 27, 2001 CNBC interview and those statements made by defendants and contained in the Company's February 5, 2001 release, reproduced herein, *supra*, were each materially false and misleading and were known by defendants to be false at that time, or were recklessly disregarded as such for the following reasons:

(a) Defendants failed to disclose the material adverse factors affecting the Company alleged in paragraphs 59-67, *supra*.

(b) Contrary to defendants' representations that the Company's stock was "undervalued in view of our prospects," defendants knew but failed to disclose that defendant Erani had sought to have stock brokers "*manipulate the market for the Company's stock.*"



Further, defendants knew but failed to disclose that the Company's ultimate prospects for achieving profitability were severely compromised by the problems alleged in paragraphs 59-67 above, including the Company's serious manufacturing and marketing problems, its inability to access as necessary adequate funding to keep the Company viable, the difficulties in achieving reimbursement for Apligraf, and the disruptive effect on operations that high turnover and infighting among the Company's senior management was having, and would continue to have for the foreseeable future.

(c) Defendant Laughlin's representation that Novartis' agreement to grant Organogenesis a \$20 million put option was evidence of Novartis' conviction that "everything is coming together" and that "yes, this is working" and "is going to be a very big business" was materially misleading and incomplete for the same reasons as alleged in subparagraph (b) above.

(d) Contrary to defendant Laughlin's representation that under the \$20 million put option with Novartis the Company was "able *at our discretion and our option* to sell Novartis \$20 million of shares" and that the put option was a "wonderful safety net to have in our pocket" was untrue. As later revealed by defendants, the Company did not have the ability to raise the full amount of that funding option at the discretion of the Company. As defendants knew but failed to disclose at the time, significant conditions precedent to the exercise of the put option prevented the Company from accessing \$10 million of the put option funding, which ultimately led to the Company's inability to fund operations in 2002. Thus, the "safety net" that defendants represented they had secured for the Company was only an illusion.

(e) Defendant Laughlin's statements that the revised Novartis marketing agreement was a "turning point" for the Company and a "major improvement in our economic situation" and that the Company would receive "a substantial increase in the percentage of the